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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,792	08/08/2006	Massimo Bani	PB60734USW	6405

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GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B475
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
4173	

NOTIFICATION DATE	DELIVERY MODE
12/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
ROSALIE.M.CHAMBERLAIN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No.	Applicant(s)	
	10/597,792	BANI, MASSIMO	
	Examiner	Art Unit	
	BARBARA FRAZIER	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,7 and 8* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 5, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method as claimed using the compound of formula (I) or a pharmaceutically acceptable salt, does not reasonably provide enablement for the solvate thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While all the wands factors have been considered only those are pertinent will be discussed.

The application is directed to the method of treatment comprising administering compounds of formula (I) (claim 8) or a pharmaceutically acceptable salt or solvate thereof. The specification is not adequately enabled as to how to make a solvate of formula (I) or the species therein.

Grant et al. (Advanced Drug Delivery Reviews, 2001) indicates that predicting the formation of solvates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice is both complex and difficult. All compounds respond differently to possible formation of solvates or hydrates. Therefore, Grant et al. indicates that generalizations cannot be made for a series of compounds and their respective solvates (page 18, section 3.4).

Thus, in the absence of working examples there is no showing that the instant compounds will form solvates. Since it is clear that merely bringing the compound into contact with a solvent does not automatically result in a solvate, additional direction or guidance is needed to make them, and the specification has no such direction or guidance. Therefore, only the chemically structurally defined chemicals, but not the full breadth of the claims meet the enablement requirement provision of 35 USC § 112, first paragraph.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 5, 7, and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Melotto.

The claimed invention is drawn to a method of treatment of social phobia which comprises administering to a human in need thereof an effective amount of the compound of formula(I), namely, [2-methoxy-5-(5-trifluoromethyl-tetrazol-1-yl-benzyl)]-([2S,3S]-2-phenyl-piperidin-3-yl)-amine (see claims 5 and 7).

Melotto discloses a method for the treatment of anxiety in a mammal including a human, which comprises treating said animal with therapeutically effective amount of a combination which includes the compound of formula(I) (see claims 16 and 1). Melotto teaches that the term anxiety includes social phobia (social anxiety disorder) (page 7, lines 28 and 32). Additionally, Examples 1-6 disclose Compound A (i.e., the compound of the claimed invention) as the dihydrochloride salt. Therefore, the method of Melotto anticipates the method of Melotto.

6. Claims 5, 7, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Melotto.

The claimed invention is drawn to a method of treatment of social phobia which comprises administering to a human in need thereof an effective amount of the compound of formula(I), namely, [2-methoxy-5-(5-trifluoromethyl-tetrazol-1-yl-benzyl)]-([2S,3S]-2-phenyl-piperidin-3-yl)-amine (see claims 5 and 7).

Melotto discloses a method for the treatment of anxiety in a mammal including a human, which comprises treating said animal with therapeutically effective amount of a combination which includes the compound of formula(I) (see claims 16 and 1). Melotto teaches that the term anxiety includes social phobia (social anxiety disorder) (page 7, lines 28 and 32). Additionally, Examples 1-6 disclose Compound A (i.e., the compound of the claimed invention) as the dihydrochloride salt. Therefore, the method of Melotto anticipates the method of Melotto.

It appears that the applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 5, 7, and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19 and 20 of copending Application No. 10/552,870. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '870 are drawn to a method for the treatment of anxiety

comprising administering a therapeutically effective combination which includes the compound as described in claims 5 and 8 of the claimed invention, and one skilled in the art would understand "anxiety" to include social phobia, based on the definition given in the parent international application of '870 (see WO 2004/91617, page 7, lines 28 and 32).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

9. Claim 7 is objected to because of the following informalities: it appears that the term "dichloride" is a typographical error, and is intended to mean "dihydrochloride", as taught in the specification (see page 6, line 40 and page 7, line 14). Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Frazier whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 8am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718, or Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 4173